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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/418,870	04/07/95	VAN NEST	G 0085.006

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EXAMINER

WORTMAN, D

ART UNIT	PAPER NUMBER
1645	58

DATE MAILED: 01/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/418,870	Applicant(s) Van Nest et al.
	Examiner Donna C. Wortman, Ph.D.	Group Art Unit 1645

Responsive to communication(s) filed on Nov 15, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-5, 7-9, 29, 36, 38, and 39 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-5, 7-9, 36, 38, and 39 is/are rejected.

Claim(s) 29 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 36, 38 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Woodard et al. in view of Silvestri et al., for reasons of record in rejecting 1-5, 7-9, 29, 36, 38 and 39 previously.

Applicant has argued that there is no suggestion in either of the cited references to alter the prior art formulations to arrive at applicant's adjuvant composition; that the supporting "Declaration-94," "Declaration-97," Examples 1-4 of the instant specification, and the Ott et al. reference establish surprisingly superior adjuvant properties of the claimed adjuvant compositions; that Woodard's compositions are used as vehicles for adjuvants and not as adjuvants, and that Woodard's affidavit concludes that the success as adjuvants of emulsions of the instant invention was an "outstanding finding"; that Woodard teaches that the antigen must be added to the internal phase of the emulsion for optimal antibody response, while for the instant compositions the

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antigen is co-administered with the preformed emulsion; that Silvestri states that submicron systems are investigated primarily because they are more stable than other emulsions and that they are useful as drug delivery systems and not as adjuvants. Applicant argues that there is no motivation to combine the two references to arrive at the claimed adjuvant formulations.

Applicant's arguments and all the supporting documents have been considered but not found persuasive for the following reasons. First, claims 1-5, 7-9, 36, 38 and 39 are drawn to compositions consisting essentially of a metabolizable oil and an emulsifying agent, wherein the oil and the emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are less than 1 micron in diameter. The composition has no block copolymer and no muramyl peptide, and is recited as capable of increasing the immune response to an antigen when administered with the antigen. Both Woodard and Silvestri deal with the desirability of making stable oil-in-water emulsions and teach how to vary the relevant parameters to achieve stability; one of the relevant parameters is droplet size. Both Woodard and Silvestri produce stable oil-in-water emulsions that make it obvious to arrive at the instantly claimed compositions, regardless of whether they call them "adjuvants" or stable emulsions, or vehicles. The recitation "adjuvant" and/or "capable of increasing ..." may represent newly recognized properties of a stable oil-in-water emulsion, but such recitation is not seen to distinguish over the prior art compositions. Further, the evidence of unexpected results is not persuasive with respect to the composition claims because it appears

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that applicant has merely recognized a new use for an otherwise obvious composition.

Claim 29 is objected to as dependent upon a rejected claim, but would be allowable if rewritten to include all the limitations of the rejected base claim. The prior art of record would not make it obvious to administer an antigen in the presence of a pre-formed oil-in-water emulsion as claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna

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Wortman, Art Unit 1645, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1645 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.



Donna C. Wortman, Ph.D.
Primary Examiner

January 28, 2000